

MAR - 2 2004

**510(k) Summary**

1. SUBMITTED BY: Bruce A. MacFarlane, Ph.D.  
5182 West 76<sup>th</sup> Street  
Edina, MN 55439  
USA  
Summary prepared: 26 November 2003
2. NAME OF DEVICES:
- |                            |  |
|----------------------------|--|
| Trade Name:                | DiaScreen® Reagent Strips for Urinalysis   |
| Common Names/Descriptions: | Urine Test Strips  |
| Classification Names:      | Ketones (nonquantitative) test system<br>Urinary glucose (nonquantitative) test system |
| Regulatory Status:         | Class II   |
3. PREDICATE DEVICE: DiaScreen® Reagent Strips for Urinalysis
4. DEVICE DESCRIPTION:

DiaScreen® Reagent Strips for Urinalysis are plastic strips coated with one or more dry reagents. Each reagent is specific for a particular analyte. Reagent areas are spaced along the test strip, with a physical gap between reagent areas. Three configurations are designed for both professional and home use: detecting one or both of the following analytes:

- glucose
- ketone

The dry reagents change color in reaction to the presence, and concentration, of their associated analyte. The strips are read visually against a color chart.

5. INTENDED USE:

DiaScreen® Reagent Strips for Urinalysis are dip-and-read test strips intended for use as an *in vitro* diagnostic aid using urine specimens. DiaScreen Reagent Strips provide qualitative and semiquantitative tests for ketone, and glucose by visual comparison to a color chart. The tests provided are considered routine urinalysis.

## 6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

DiaScreen® Reagent Strips for Urinalysis are plastic strips coated with one or more dry reagents. Each reagent is specific for a particular analyte. Reagent areas are spaced along the test strip, with a physical gap between reagent areas. Several product configurations are commercially available, detecting one or more of the following analytes: specific gravity, pH, blood, leukocytes, nitrite, protein, bilirubin, ketone (acetoacetic acid), glucose, and urobilinogen. The dry reagents change color in reaction to the presence, and concentration, of their associated analyte. The present premarket notification encompasses the ketone and glucose analytes only.

## 7. NON-CLINICAL TESTING

Not applicable.

## 8. CLINICAL TESTING

Clinical data indicate that home users can obtain accuracy which is substantially equivalent to that obtained by professional users.

## 9. CONCLUSIONS FROM TESTING

Testing demonstrated that performance of the test strips with new labeling is appropriate for Over-the-Counter home usage.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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Bruce A. MacFarlane, Ph.D.  
VP, Regulatory Affairs And Quality Systems  
Hypoguard USA, Inc.  
5182 West 76<sup>th</sup> Street  
Edina, MN 55439

Re: k033851  
Trade/Device Name: Dia Screen<sup>®</sup> Reagent Strips for Urinalysis  
Regulation Number: 21 CFR 862.1340  
Regulation Name: Urinary glucose (non-quantitative) test system  
Regulatory Class: Class II  
Product Code: JIL; JIN  
Dated: November 26, 2003  
Received: December 17, 2003

Dear Dr. MacFarlane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

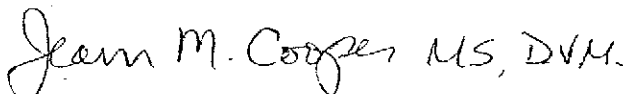
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in dark ink, reading "Jean M. Cooper MS, D.V.M." in a cursive style.

Jean M. Cooper, MS, D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K033851

Device Name: DiaScreen® Reagent Strips for Urinalysis

### Indications For Use:

DiaScreen® Reagent Strips for Urinalysis are intended for the qualitative and semi-quantitative measurement of glucosuria (glucose in urine). These measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, hypoglycemia, and hyperglycemia.

DiaScreen® Reagent Strips for Urinalysis are intended for the qualitative and semi-quantitative measurement of ketones in urine. Identification of ketones is used in the diagnosis and treatment of acidosis or ketosis and for monitoring patients on ketogenic diets and patients with diabetes.

Testing can be done by dipping the Reagent Strips into a specimen container or by holding them directly in the urine stream.

The glucose and ketone strips are intended for both professional and over-the-counter use.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson  
Division Sign-Off

Office of In Vitro Diagnostic  
Device Evaluation and Safety

510(k) K033851